K073139

4. 510(k) Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87.

Establishment Registration Number:	2021898
Address of Manufacturer:	Medtronic Neurosurgery 125 Cremona Drive Goleta CA, 93117 (805) 968-1546 ext. 1773 Fax: (805) 968-9336
Contact Person:	Jeffrey Henderson
Date:	November 5, 2007
Trade or Proprietary Name:	Small Lumen Peritoneal Catheter
Common usual or Classification Name:	Central nervous system fluid shunt and components (882.5550)
Predicate Device Identification:	CSF-Cardiac/Peritoneal Catheter (K792005)

JAN 30

Description: The Small Lumen Peritoneal Catheter is fabricated from radiopaque silicone elastomer tubing with a barium-impregnated core encapsulated in a clear silicone outer sheath. An enlarged end allows connection to Medtronic Neurosurgery's PS Medical cerebrospinal fluid shunting valves. The distal segment of the catheter contains no wall slits and the tip is open ended. A silicone elastomer fixation tab is included. It is designed to secure the catheter to surrounding fascia. This catheter is not indicated for placement into the right atrium of the heart.

Intended Use: The Small Lumen Peritoneal Catheter is the distal component of a cerebrospinal fluid shunt system for use in shunting cerebrospinal fluid into the peritoneal cavity.

Intended Use of predicate device(s): The CSF-Cardiac/Peritoneal Catheter is the distal component of a cerebrospinal fluid shunt system for use in shunting cerebrospinal fluid into the right atrium of the heart or the peritoneal cavity.

Technological Comparison: Medtronic Neurosurgery submits that the materials of fabrication, intended use, and the fundamental scientific technology of the Small Lumen Peritoneal Catheter are the same as the previously reviewed and cleared CSF Cardiac/Peritoneal Catheter. Based upon the summary above,

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Medtronic Neurosurgery determines substantial equivalence, safety, and efficacy of the Small Lumen Peritoneal Catheter compared to the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 2008

Medtronic Neurosurgery
% Mr. Jeffrey Henderson
Vice President, Quality &
Regulatory Affairs
125 Cremona Drive
Goleta, California 93117-5500

Re: K073139
Trade/Device Name: Small Lumen Peritoneal Catheter
Regulation Number: 21 CFR 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: January 10, 2008
Received: January 11, 2008

Dear Mr. Henderson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

II. Statement of Indications for Use

510(k) Number (if known): K073139

Device Name: Small Lumen Peritoneal Catheter

Indications for Use:

The Small Lumen Peritoneal Catheter is designed as the distal component of a cerebrospinal fluid shunt system for use in shunting cerebrospinal fluid into the peritoneal cavity.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073139